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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/018,451	03/07/2002	Ernst Bernhard Grabitz	205,360	4546

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EXAMINER

SRIVASTAVA, KAILASH C

ART UNIT	PAPER NUMBER
1651	(6)

DATE MAILED: 08/08/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>
	10/018,451	GRABITZ, ERNST BERNHARD
	<b>Examiner</b>	<b>Art Unit</b>
	Dr. Kailash C. Srivastava	1651

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

**A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.**

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) Responsive to communication(s) filed on June 19, 2003 as Paper Number 09.
- 2a) This action is **FINAL**.                    2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) Claim(s) 1-24 is/are pending in the application.
- 4a) Of the above claim(s) 16-24 is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) 1-15 is/are rejected.
- 7) Claim(s) \_\_\_\_\_ is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) The proposed drawing correction filed on \_\_\_\_\_ is: a) approved b) disapproved by the Examiner.  
 If approved, corrected drawings are required in reply to this Office action.
- 12) The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All b) Some \* c) None of:  
 1. Certified copies of the priority documents have been received.  
 2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
 a) The translation of the foreign language provisional application has been received.
- 15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- |  |  |
|--|--|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ . |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                               | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)  |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>4&amp;7</u> . | 6) <input type="checkbox"/> Other: _____                                     |

## DETAILED ACTION

1. Applicant's election with traverse of Group I, Claims 1-15 filed June 09, 2003 as Paper Number 9 to election requirement in Office Action mailed May 19, 2003 as paper number 8 is acknowledged and entered. Applicants' traversal is on the ground (s) that the instant application was filed under §371 and as such applicants are entitled to "a unity of invention standard" and a search of all the groups would not place an additional burden on the examiner. Applicant further argues that the subject matter claimed in Claims 1-8 is drawn to an inactivated microorganism, whereas that of claims 9-15 to a composition comprising those microorganisms. Applicant also argues that the Competent ISA has not raised the same objections because the claimed invention in the present application meets the requirements of PCT Rule 13(2).

Applicant's arguments have been carefully considered, but are not found persuasive because of the reasons of record on page 2, item 3 in Office Action mailed May 19, 2003 as paper number 8 and for additional reasons as discussed below.

Examiner has grouped the inactivated microorganisms and the composition comprising those microorganisms (i.e., claims 1-15) in Group I because said microorganisms are a composition of matter. The invention of Group I is drawn to a first product, i.e., inactivated microorganisms, in and of itself; said product/composition is obtained from growing and inactivating said microorganism and subsequently using said microorganisms in the composition comprising said inactivated microorganism. Inventions of Groups II-III lack this special technical feature because they are drawn to two different methods, each having a different functional effect. Furthermore, subject matter of claimed invention, i.e., nutritional compositions comprising inactivated microorganisms does not contribute over known prior art (e. g., U.S. Patent 5,108,764). Also, the first product and its first method of use (i.e., claims 1-15) follow U.S.C. §371 practice with regard to unity of invention (i.e., Group I). However, additional claims drawn to subsequent methods of preparing the inactivated microorganisms follow typical US restriction practice because claims encompassed in Groups II-III each are drawn to two different methods of preparing the inactivated microorganism. Additionally, the search for each of the distinct inventions of Groups I-III is not co-extensive particularly with regard to the literature search. Further, a reference that would anticipate the invention of one group would not necessarily anticipate or even make obvious another group. Finally, the condition for patentability is different in each case. Thus, it will be an undue burden to examine all of the inventive Groups in one application. The restriction requirement is, therefore, still deemed proper and is made FINAL.

Accordingly, Claims 16-24 are withdrawn from further consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03. Examiner suggests that the non-elected claims cited above be canceled in response to this Office action to expedite prosecution.

2. Claims 1-15 are examined on merits.

### **Information Disclosure Statement**

3. Applicant's Information Disclosure Statements (i.e., IDSs) filed March 7, 2002 as Paper Number 4 and on August 26, 2002 as Paper Number 7 have been entered. Since IDS filed on August 26, 2002 is a duplicate of the one filed on March 7, 2002, IDS filed on March 07, 2002 as Paper Number 4 has been considered.

### **Priority**

4. Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

### **Claim Rejections Under 35 U.S.C. § 112**

5. The following is a quotation of the second paragraph of 35 U.S.C. § 112:

*The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.*

6. 35 U.S.C. 101 reads as follows:

*Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.*

7. Claims 1, 4-7 and 12-15 are rejected under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

- Claims 1 and 4-7 as written are very confusing, difficult to understand and thus indefinite. Applicants is requested to clearly, concisely and succinctly rewrite the claims in such a manner that the claims clearly indicate the applicant's invention.
- The recitation "use" in Claims 13-15 renders those claims indefinite because it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.
- Claims 13-15 are rejected under 35 U.S.C. §101 because the claimed recitation of a use as explained above, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. §101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd. v. Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).
- The phrase "are chosen in the group" in claims 1 and 4-5 renders those claims indefinite because said phrase does not clearly define the claimed subject matter. Examiner

suggests that the applicant should replace the phrase "are chosen in the group" with the phrase "are selected from the group".

- The phrase "active principles of vegetable origin" in claim 4 renders that claim indefinite because the metes and bounds for the said phrase are not defined. Applicant should define the phrase "active principles of vegetable origin".
- The phrase, "said fish are in the early stages of growth" renders claim 12 indefinite because the phrase "early stages of growth" in and by itself does not establish metes and bounds. Applicant should clearly define the exact growth stage of fish in context of the claimed invention.

All other claims depend directly from the rejected claims (1, or 4) and are, therefore, also rejected under 35 U.S.C. §112, second paragraph for the reasons set forth above.

### ***Claim Rejections – 35 U.S.C. § 102***

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action:

***A person shall be entitled to a patent unless –***

***(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.***

9. Claims 1 and 4-7 are rejected under 35 U.S.C. §102(b) as anticipated by Pannell (U.S. Patent 5,288,632) with evidence provided by Gruenwald et al (eds. PDR for Herbal Medicines. 1998. Medical Economics company, Montvale, N.J., Pgs. 836-839).

Pannell's invention teaches microbially encapsulated materials comprising a grown intact microbe such as a fungus, bacterium, algae, preferably *Saccharomyces cerevisiae* is harvested and subsequently, materials such as eucalyptus oil and vitamins (e.g., A and C) or other compounds are encapsulated in said microbe through mixing the microbe with liquid forms of those materials, said composition, i.e., encapsulated inactivated *Saccharomyces cerevisiae* cells encapsulating bioflavonoid and vitamins separated through centrifugation and freeze-dried (Column 2, Lines 26-66; Column 3, Lines 31-57; Column 4, Lines 55-62 and Column 6, Lines 40-49). Eucalyptus comprises bioflavonoids, wherein one of the bioflavonoid is rutin (See Gruenwald et al., Page 837; Column 1, Lines 25). Thus, Pannell teaches a yeast biocapsule encapsulating bioflavonoids and vitamins. Pannell further teaches "Usually the microbe will be killed as a result of the encapsulation" (Column 4, lines 38-39).

Therefore, the reference is deemed to anticipate the cited claims.

In this rejection under 35 U.S.C. §102(b), Gruenwald et al., is cited to merely support that the eucalyptus oil/extract is comprised of bioflavonoids, wherein rutin is the bioflavonoid and not as a prior art reference.

10. Claims 1, 4 and 9-15 are rejected under 35 U.S.C. §102(b) as anticipated by Sagar et al. (WO 94/22572).

Sagar et al. teach that it is well known in the art to encapsulate a variety of substances/nutritional ingredients in dead (i.e., inactivated) or alive microorganisms such as yeast cells, bacteria, algae and microfungi, wherein such preparations are known as biocapsules. The nutritional value of said biocapsules is enhanced by encapsulating nutriceutical materials (e.g., amino acids and fish oils) in said biocapsules. Thus prepared biocapsules are applicable as feed for fish larvae, wherein, said biocapsules (i.e., nutrients encapsulated in yeast cells) can be tailored according to particular nutritional needs for each stage of growing fish larvae (Page 1, Lines 8-9; Page 3, Lines 9-24 and Page 4, Lines 4-15). Thus, Sagar et al. teach an animal feed composition for each stage of growing fish larvae, said animal feed comprising inactivated yeast cells (i.e., biocapsaules), wherein nutrients such as amino acid and fish oil are encapsulated in said inactivated yeast cells.

Therefore, the reference deems to anticipate the cited claims.

### ***Claim Rejections - 35 U.S.C. § 103***

11. The following is a quotation of 35 U.S.C. §103(a) which forms the basis for all obviousness rejections set forth in this Office action:

***(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.***

12. Claims 1-15 are rejected under 35 U.S.C. § 103 (a) as obvious over Pannell (U.S. Patent 5,288,632) with evidence provided by Gruenwald et al., in view of Sagar et al. (WO 94/22572).

As discussed *supra*, Pannell with evidence provided by Gruenwald et al. teach biocapsules obtained from inactivated *Saccharomyces cerevisiae*, wherein said biocapsules encapsulate bioflavonoids (e.g., rutin) and vitamins (e.g., A and C). Pannell, however, does not teach that said biocapsules are applicable as feed for fish larvae, wherein, said biocapsules (i.e., nutrients encapsulated in yeast cells) are applicable as feed ingredient for each stage of growing fish larvae.

Sagar et al. teach an animal feed composition for each stage of growing fish larvae, said animal feed comprising inactivated yeast cells (i.e., biocapsaules), wherein nutrients such as amino acid and fish oil are encapsulated in said inactivated yeast cells.

One having ordinary skill in the art would have been motivated to modify Pannell's teachings with those of Sàgar et al. to incorporate different nutrients (i.e., bioflavonoids, vitamins, amino acids and oils) in said *Saccharomyces cerevisiae* biocapsule and to obtain an animal feed composition comprising said biocapsule, wherein said animal feed is fed to an animal, namely growing fish larvae; because the prior art references teach compositions comprising inactivated yeasts, wherein antibacterial compounds or nutrients, or nutriceuticals have been encapsulated in inactivated yeast cells. Thus, Pannell remedies deficiencies of incorporating bioflavonoids and vitamins in yeast biocapsules (Column 2, Lines 26-66; Column 3, Lines 31-57; Column 4, Lines 55-62 and Column 6, Lines 40-49 and Gruenwald et al., Page 837, Column 1, Lines 25) and Sagar et al. remedy deficiencies of incorporating other nutrients (e.g., amino acid) in said inactivated *Saccharomyces cerevisiae* (i.e., yeast) cells (i.e., biocapsules) and incorporating said biocapsules in animal feed for growing fish larvae (Page 1, Lines 8-9; Page 3, Lines 9-24 and Page 4, Lines 4-15).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify Pannell' teachings with Sagar et al. to incorporate different nutrients in said inactivated *Saccharomyces cerevisiae* (i.e., yeast) cells (i.e., biocapsule) and to obtain an animal feed composition comprising said biocapsule for growing fish larvae because both the prior art references teach compositions comprising inactivated yeasts, wherein nutriceuticals have been encapsulated in inactivated yeast cells. Pannell remedies the deficiencies of incorporating bioflavonoids and vitamins in yeast biocapsules in Sagar et al., while Sagar et al. remedy deficiencies in Pannell's teachings, because Sagar et al. teach a yeast biocapsule and incorporating said biocapsule in animal feed for growing fish larvae.

None of the prior art references cited above teach incorporating oxytetracycline or sulfadimethoxine as an antibacterial compound/ antibiotic in their composition. However, the adjustment of particular conventional working conditions (e.g., choice of an antibiotic or substitution of an antibacterial compound with another antibacterial compound having same functional effect) is deemed merely a matter of judicious selection and routine optimization, which is well within the purview of the skilled artisan.

From the teachings of the cited prior art references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

## Conclusion

13. No Claims are allowed.

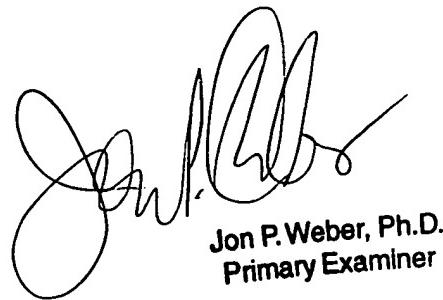
14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Kailash C. Srivastava whose telephone number is (703) 605-1196.  
The examiner can normally be reached on Monday-Thursday from 7:30 A.M. to 6:00 P. M. (Eastern Standard Time or Eastern Daylight Saving Time).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn, can be reached on (703) 308-4743 Monday through Thursday. The fax phone number for the organization where this application or proceeding is assigned is (703) 305-3014.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

~~Kailash~~ C. Srivastava, Ph.D.  
Patent Examiner  
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August 7, 2003



Jon P. Weber, Ph.D.  
Primary Examiner